

Message Text

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ORIGIN HEW-06

INFO OCT-01 AF-10 ARA-14 EUR-12 ISO-00 OES-07 /050 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

-----003898 300626Z /21

P R 292317Z JUN 77

FM SECSTATE WASHDC

TO AMEMBASSY MEXICO PRIORITY

AMCONSUL SAO PAULO PRIORITY

AMEMBASSY ROME PRIORITY

AMEMBASSY ATHENS PRIORITY

AMEMBASSY MADRID PRIORITY

AMEMBASSY PRETORIA PRIORITY

AMEMBASSY CARACAS PRIORITY

AMEMBASSY SANTIAGO PRIORITY

AMEMBASSY KINGSTON PRIORITY

INFO AMEMBASSY BRASILIA

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E.O. 11652: N/A

TAGS:OGEN,ETRD,EIND,TBIO,MX,BR,IT,GR,SP,SF,VE,JM,CI

SUBJ : FDA ADVISORY - POTENTIAL ELECTRIC HAZARD
IN MEDICALDEVICE(DEFIBRILLATORS) - "RECALL" T-013-7

1. FDA ADVISES OF THE FOLLOWING "RECALL" -

PRODUCT INVOLVED:

ELECTRONICS FOR MEDICINE, ISOLATED DEFIBRILLATOR, MODELS
MSD AND ISD - 23. BOTH MODELS ARE LOW-N-TYPE DC DEFIB-
RILLATORS, AND ARE INTENDED TO STOP FIBRILLATION OF THE
HEART BY USING ELECTRICAL ENERGY. ONLY MODELS MSD AND ISD-
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23 ISOLATED DEFIBRILLATORS ARE BEING RECALLED. NO OTHER
MODELS OF THIS FIRM'S DEFIBRILLATORS ARE INVOLVED. EACH
UNIT IS LABELED ON THE FRONT DISPLAY PANEL, WITH MODEL
DESIGNATION AND MANUFACTURER, ELECTRONICS FOR MEDICINE-
ISOLATED DEFIBRILLATOR. ALL LOTS OF MODELS MSD AND ISD -
23 ARE UNDER RECALL.

MANUFACTURER/RECALLING FIRM:

ELECTRONICS FOR MEDICINE, 30 VIRGINIA ROAD, WHITE PLAINS,
NEW YORK 10603.

2. REASON FOR "RECALL":

AS A RESULT OF A COMPLAINT INVOLVING 2 MODEL MSD DEFIB-
RILLATORS, AND INSPECTION OF THE FIRM WAS PERFORMED DURING
APRIL AND MAY 1976. INSPECTION DISCLOSED THAT TRANSISTOR
2N3638 OR REPLACEMENT TRANSISTOR 2N4249 IN THE CONTROL
CIRCUIT OF EITHER AN MSD OR ISD - 23 DEFIBRILLATOR CAN
FAIL UNDER CERTAIN CIRCUMSTANCES. AS A RESULT OF FAILURE
THE DEFIBRILLATOR WILL CHARGE TO MAXIMUM ENERGY WHENEVER
THE "CHARGE BUTTON" IS PRESSED, REGARDLESS OF THE SETTING
ON THE WATT-SECOND CONTROL. THIS FAILURE WAS NOTED IN A
FEW DEFIBRILLATORS USING USING THE ADULT, SHIELDED (RED,
HIGH VOLTAGE) PADDLE CABLES TO THE MAXIMUM LEVEL OF STORED
ENERGY (500 WATT-SECONDS) AND DISCHARGED AT INTERVALS OF
LESS THAN 30 SECONDS. THESE SHIELDED-PADDLE CABLES BUILT
UP A CAPACITANCE IN THE SHIELD FROM THEIR STORED ENERGY
WHICH CAUSES THE REFERENCED TRANSISTOR TO FAIL. THE FIRM
DEVELOPED A SPECIALLY ENCAPSULATED TRANSISTOR WHICH COULD
OVER COME THIS CAPACITANCE, AND NOT FAIL. THE FIRM
PLANNED TO MODIFY ALL MODEL MSD AND ISD-23 ISOLATED DE-
FIBRILLATORS BY REPLACING THE POTENTIALLY FAULTY TRANS-
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ISTOR WITH THE SPECIALLY ENCAPSULATED ONE. AT THE CON-
CLUSION OF EACH MODIFICATION, A PRESSURE SENSITIVE LABEL
WOULD BE AFFIXED TO THE BACK OF EACH UNIT MODIFIED. THIS
PRESSURE SENSITIVE LABEL APPROXIMATELY ONE-INCH IN LENGTH
PRINTED IN BLACK INK ON A WHITE BACKGROUND WILL BEAR THE
FOLLOWING INFORMATION "ELECTRONICS FOR MEDICINE XXX 1312
XXX FIELD CORRECTION". THE NO. 1312 REFERS TO THE MANU-
FACTURERS MODIFICATION LOGUE WHICH SHALL DESCRIBE THIS
MODIFICATION.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE BEEN ADVISED BY THE FIRM OF
THE DETAILS OF THE PROBLEM AND THE MODIFICATION REQUIRED.
ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY
SHOULD BE DIRECTED TO THE FIRM.

4. CONSIGNEES AS FOLLOW:

SEARLE NUCLEAR DO BRAZIL RUA TEODORO SAMPAIO 417-60
ANDAR/CONJ.63/74/05405, SAO PAULO - SP BRAZIL, ENG.
WALTER RAUTIGNEN, MKTG. MGR (EVARISTO CARLINI, TECH.MGR)

67287 - 7/16/74 - DR. FLORENZINO MIRANDO, SAO PAULO,

68513 - 9/18/74 - COMPANHIA DO GRANDES, SAO PAULO,

66301 - 6/12/74 - SOCOR-SOCORRO, AO CORACAO S/A
RUA TUPIS, 1578
BELO HORIZONTE - MG 30.000, BRAZIL

AGENT-O.T.E. BIOMEDICA S.P.A./VIA DI CACIOLLE, 15/50127-
FIRENZE/ITALY - ATT; MR. A. MOTTA

67254 - 7/15/74 OSPEDALE SALVATORE, ITALY

67316 - 7/17/74 RES MEDICIS, MILAN, ITALY

69677 - 11/1/74 OSPEDALE SALVINO, MILAN, ITALY
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69680 - 11/1/74 OSPEDALE SALVINO, MILAN, ITALY

AGENT-ELECTRATHA/PH. ATHANASSOULAS AND CO. 64 ACADEMIAS
AVE. ATHENS 134, GREECE

67639 - 8/7/74 V.A. HOSPITAL, ATHENS, GREECE

AGENT-ATAIO, INGENIEROS, S.A. ENRIQUE LARRETA 12/MADRID
16, SPAIN

68031 - 8/28/74 ATAIO, MADRID, SPAIN

69402 - 10/29/74 CENTRO MEDICO, SANTANDER, SPAIN

69413 - " CENTRO MEDICO, SANTANDER, SPAIN

AGENT - PROTEA ELECTRO MEDICAL/7 NEWTON STREET, WEMMER,
JOHANNESBURG, SO AFRICA

68977 - 10/8/74 PROTEO ELECTRO-MED. JOHANNESBURG

AGENT-DR. MARCOS MANDELBLUM/FARADAY, S.A./P.O. BOX 80117
CARACAS, VENEZUELA

70131 - 11/27/74 FARADAY, CARACAS, VENEZUELA

AGENT-EQUIPO PARA HOSPITALES/TONALA 161/MEXICO CITY, 7
D.F., MEXICO ATTN: MR. E. DE LA TORRE 905

62078 1/23/74

CATHOLIC UNIVERSITY HOSPITAL-MARCOLETTA 377, SANTIAGO,
CHILE

62655 1 12/12/74
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UNIVERSITY HOSPITAL OF THE WEST INDIES, MONA STREET,
ANDREW, KINGSTON, JAMAICA, WEST INDIES

64272 4/2/74 - UNIV. HOSPITAL, KINGSTON, WEST INDIES

FORMED
RUA SOROCAHA 584-ZC-02
RIO DE JANEIRO - R.J., BRAZIL VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 29-Jun-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE151933
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770233-0514
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977066/aaaaaera.tel
Line Count: 184
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 39cd417d-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
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Review Exemptions: n/a
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Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2159774
Secure: OPEN
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Subject: FDA ADVISORY - POTENTIAL ELECTRIC HAZARD IN MEDICALDEVICE(DEFIBRILLATORS) - "RECALL" T-013-7
TAGS: OGEN, ETRD, EIND, TBIO, MX, BR, IT, GR, SP, SF, VE, JM, CI, ELECTRONICS FOR MEDICINE
To: MEXICO SAO PAULO MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/39cd417d-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
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